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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,144	04/03/2001	Matthias Krause	M0656/7065	1823

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WOLF GREENFIELD & SACKS, PC
FEDERAL RESERVE PLAZA
600 ATLANTIC AVENUE
BOSTON, MA 02210-2211

EXAMINER

HADDAD, MAHER M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/825,144

Applicant(s)

KRAUSE ET AL.

Examiner

Mahe M. Haddad

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-2, 4, 6, 9, 26, 30, 34, 39, 42, 46, 73-74 and 78-84 is/are pending in the application.
- 4a) Of the above claim(s) 6, 9, 34, 46 and 84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 26, 30, 39, 42, 73-74 and 78-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 6/7/04, is acknowledged.
2. Claims 1-2, 4, 6, 9, 26, 30, 34, 39, 42, 46, 73-74 and 78-84 are pending.
3. Claims 6, 9, 34, 46 and 84 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.
4. Claims 1-2, 4, 26, 30, 39, 42, 73-74 and 78-83 are under examination as they read on a method for inhibiting cytoskeletal rearrangement, a method for inhibiting a T cell response, and a method for increasing platelet aggregation with an EVH1 binding peptide
5. In view of the amendment filed on 6/7/04, only the following rejections are remained.
6. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
8. Claims 1-2, 4, 26, 30, 39, 42, 73-74 and 78-83 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inhibiting cytoskeletal actin rearrangement in a T cell or a platelet, a method for inhibiting a T cell response and a method for increasing platelet aggregation comprising contacting the T cell or platelet with an amount of a Fyb/SLAP complex inhibitor sufficient to inhibit the formation of a complex of an Ena/VASP protein and a Fyb/SLAP protein wherein the Fyb/SLAP inhibitor is EVH1 binding peptide FPPPP (SEQ ID NO:15), does not reasonably provide enablement for a method for inhibiting cytoskeletal rearrangement in a lymphocyte, macrophage, or platelet comprising contacting the lymphocyte, macrophage, or platelet with an amount of any "Fyb/SLAP complex inhibitor" that binds Fyb/SLAP or Ena/VASP proteins sufficient to inhibit the formation of a complex of an Ena/VASP protein and a Fyb/SLAP protein in claim 1, a method for inhibiting a T cell response to T cell receptor stimulation comprising: contacting a T cell with an amount of any "Fyb/SLAP complex inhibitor" sufficient to inhibit formation of a complex of a Fyb/SLAP protein and an Ena/VASP protein in the T cell in claim 26; a method for increasing platelet aggregation, comprising: contacting a platelet aggregation, comprising contacting a platelet with any "Fyb/SLAP complex inhibitor" to inhibit formation of a complex of a Fyb/SLAP protein and an Ena/VASP protein in the platelet in claim 39, wherein any "Fyb/SLAP complex inhibitor" binds to the EVH1 domain of the Ena/VASP protein and inhibits binding of the Ena/VASP protein to Fyb/SLAP protein in claims 2, 30 and 42, wherein the Fyb/SLAP complex inhibitor is any "EVH1 binding peptides" in claims 74, 80 and 83, wherein the Fyb/SLAP complex inhibitor "comprises" the peptide FPPP (SEQ ID NO:15) or any "peptide mimetic having an equivalent binding specificity" in claims 4, 79 and 82. The specification does not enable

Art Unit: 1644

any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims essentially for the same reasons set forth in the previous Office Actions mailed 7/30/02, 2/12/03 and 12/03/03.

Applicant's arguments, filed 6/07/04, have been fully considered, but have not been found persuasive.

Applicant asserts that a representative number of compounds that fall within the scope of the claim are provided in the specification as filed. Applicant asserts that a representative number of inhibitors are described at page 8, line 18 through page 9 line 6 of the specification. Applicant asserts that the specification describes inhibitor comprising SEQ ID NO:5 (FPPPP) as well as additional inhibitors such as: Act A repeats, EVHI binding peptides, ScarWA, and dominant negative Fyb/SLAP fragments. Preferred inhibitors described in the specification include molecules having at least one acidic amino acid on one or both sides of the FPPPP sequence, and "reverse change variants" having at least one basic amino acid on one or both sides of the FPPPP sequence. Additional inhibitors include EVHI domain containing proteins, Ena/VASP fragments, and antibodies or antibody fragments that bind Fyb/SLAP protein or Ena/VASP protein. The person of skill in the art is familiar with each of these known molecules. Applicants also provided inhibitors that are mimetics for the FPPPP peptide, i.e., they compete with FPPPP for binding to the EVHI domain.

Applicant's disclosure of additional "compounds" in the instant specification appears to be limited to FPPPP (SEQ ID NO: 15) comprising sequences. For example, ActA repeat: consensus sequence **DFPPPTDEEL**, and EVH1 binding peptide is the same as ActA repeat. The specification is silent regarding the dominant negative Fyb/SLAP fragments and Scar-WA inhibitors (proline-rich sequences with three consensus motifs LPPPP). Therefore, such compounds do not provide additional insight into the identification of a representative number of species to provide support for the broadly claimed genera. Therefore, the specification neither discloses any such compound nor provides any suggestion as to how such a compound could be made or otherwise obtained other than by trial-and-error research.

Accordingly, the specification fails to provide a representative number of compounds that fall within the scope of the claims to enable one skill in the art to practice the claimed invention without undue experimentation.

A "representative number of species" mean that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. See MPEM 2100-164 (ii).

9. Claims 1-2, 4, 26, 30, 39, 42, 73-74 and 78-83 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification

Art Unit: 1644

in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the same reasons set forth in the previous Office Actions mailed 7/30/02, 2/12/03 and 12/03/03.

Applicant's arguments, filed 6/07/04, have been fully considered, but have not been found convincing.

Applicant submits that the specification provides numerous examples of Fyb/SLAP complex inhibitors, in addition to SEQ ID NO:15. Applicant contends that these Fyb/SLAP inhibitors are clear examples of molecules that inhibit the formation of a complex of a Fyb/SLAP protein and an Ena/VASP protein. Applicants contend that molecules that are useful to inhibit the complex formation are clearly described and that the identification of such inhibitors in the specification as filed, along with the teaching provided would be sufficient for one of ordinary skill in the art to use a variety of Fyb/SLAP complex inhibitors in the methods of the invention. Applicant asserts that the examples of Fyb/SLAP complex inhibitors that are provided in the specification as filed are known molecules, and that Applicant indicates through the teaching in the application as filed that these molecules are members of a genus of molecules that are useful in the claimed methods.

However, neither the exemplary embodiments nor the specification's general method appears to describe structural features, in structural terms, that are common to the genus. That is, the specification provides neither a representative number of species (Fyb/SLAP complex inhibitors) to describe the claimed genus, nor does it provide a description of structural features that are common to species (Fyb/SLAP complex inhibitors). The specification provides no structural description of Fyb/SLAP complex inhibitors other than SEQ ID NO: 15; in essence, the specification simply directs those skilled in the art to go figure out for themselves what the claimed Fyb/SLAP complex inhibitors looks like. The specification's disclosure is inadequate to describe the claimed genus of Fyb/SLAP complex inhibitors.

10. No claim is allowed.

11. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1644

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maher Haddad, Ph.D.

Patent Examiner

July 14, 2004



CHRISTINA CHAN

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600